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EXAMINER

KELLY, ROBERT M

ART UNIT PAPER NUMBER

1633

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,935

Applicant(s)

SEELEY, RANDY S.

Examiner

Robert M. Kelly

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1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Medline Abstract of Seeley, et al. (1996) American Journal of Physiology: Regulatory, Integrative, and Comparative Physiology, 40(3): R819-R823.

DETAILED ACTION

Applicant's response and amendment of 2/12/07 is entered.

Claims 1-6, 9, and 13 are amended.

Claim 14 is newly presented.

Claims 1-13 are presently pending.

Election/Restrictions

In keeping with the elections of 8/31/06 and Official Action of 10/3/06, the claims are considered with respect to RNA and hypothalamus.

The requirement was still deemed proper and was made FINAL in the Official Action of 10/3/06.

Claims 1-14 are considered with respect to the elected species.

Claim Rejections - 35 USC § 112 - clarity

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 remain, and or are newly, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and as necessitated by amendment.

Claims 1 and 13 remain rejected, and Claim 14 is newly rejected, under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps, for reasons of record and necessitated by amendment (i.e., Claim 14).

See MPEP § 2172.01. The omitted steps are: those steps required to obtain from the expression

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of a gene identified to determine a therapeutic strategy. Such missing step(s) make the claim unclear.

Claims 1, 13, and 14, newly, each recite “therapeutic strategies”. The metes and bounds of such are unclear, as the strategy does not identify what the strategy is therapeutic for. To help Applicant understand the rejection, the broadest reasonable interpretation is that the therapeutic strategy is not related to disorders relating to body weight, wasting disorders, but that only the “treating” is so-limited. Such is further exacerbated by the present claiming of “targets”, as such target may, with further experimentation, become used to determine a therapeutic strategy, but when claiming for treating the various conditions claiming, it is unclear how the therapeutic strategy has a distinct scope from that of the identification of a target.

Claims 1, 13, and 14, in their respective preambles recite “developing therapeutic strategies and/or targets for treating [] disorders ...”, however, the result is simply an analysis. It is unclear how an analysis is a target or a strategy. I.e., it would be remedial for the claims to each make clear a result that provides each of the preamble’s results required, in such manner that the Artisan would understand how it is interrelated.

With regard to the rejections of Claims 1 and 13 for reciting “a prolonged overfeeding regimen”, such rejections are withdrawn, as a “prolonged” overfeeding regimen is determined on the basis of what is normal for that specific animal.

With regard to the rejections of Claims 1 and 13 for reciting “identifying gene and/or protein expression that occur ... with the prolonged feeding regimen”, such rejections are withdrawn, because Applicant has amended claim 1 to remove “that occur in the individual with the prolonged overfeeding regimen.

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With regard to Claims 1 and 13, the limitation “volume-matched infusions” is unclear for its metes and bounds. It would appear to the Artisan that such must only include the normal caloric intake of the animal per unit time, in a volume equivalent to that provided the overfed animals, in order to be a control commensurate with the arguments provided (e.g., pp. 9-10, paragraph bridging), however, the single example only demonstrates a non-caloric diet in the same volume as the overfed group (EXAMPLE). Hence, the scope of volume-matched infusion appears to be anything, as long as the volume is equivalent to that of the overfed rats, which would necessarily also include other equally overfed rats.

With regard to the pair-fed third group of Claims 1 and 13, such appears to be equivalent to ad libitum fed animals, and hence, would be the same as ad libitum fed animals, and hence, given this interpretation, and that of the previous rejection, would collapse all three groups into a single overfed group, which have their overfeeding terminated at the end of the study, and the study is limited to gene expression during the overfeeding regimen, as delineated in claim 4. Hence, with these broadest reasonable interpretations, the claims encompass the same scope as previously claimed.

Claims 2-12 are rejected as being dependent on a rejected base claim, and not overcoming the lack of clarity in such base claim.

Response to Argument – 35 USC 112, 2nd paragraph, Clarity

Applicant’s argument of 2/12/07 has been fully considered, but is not found persuasive.

Applicant argues the claims, now reciting control groups, overcome the lack of clarity (pp. 3-4).

Such is not persuasive. First, with regard to the omission in steps, the claims will only yield, possibly, a gene or genes, and no therapeutic strategy is developed. Second, the therapeutic strategy, in its broadest reasonable interpretation is not related to the disorders relating to body weight or wasting disorder, only the “treating” is so-related in each specific case. Hence, the rejections remain for reasons of record and necessitated by amendment.

Claim Rejections - 35 USC § 112 – written description

Claims 1-13 remain, and 14 is newly, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record and necessitated by amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Argument – written description

Applicant's argument of 2/12/07 has been fully considered but is not found persuasive.

Applicant argues that by amending the claim to “developing a therapeutic strategy”, such overcomes the enablement, as there is literal support for “developing”, pp. 4-5.

Such is not persuasive. The claims each recite, in the alternative, “developing a therapeutic strategy” and “targets for ...”. As such they must have a distinct scope. In each case, the claims appear to possibly identify a gene target related to a specific condition, but in no case is a therapeutic strategy developed, nor is any disclosure given as to how to develop a specific therapeutic strategy. Hence, the Artisan would not have understood Applicant to have been in possession of a generic method to develop a therapeutic strategy.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons necessitated by amendment. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The presently rejected claims are drawn to a generic development of a generic therapeutic strategy or generic development of a generic target, for specific generic conditions, comprising several specific steps.

Applicant's specification fails provide any generic support for the generic embodiments now claimed, and only provides specific support for a single embodiment embraced by the claims (as delineated in the EXAMPLE). Further, such specific example fails to even provide any development, but is only prophetic; and is not intended to limit the scope of the claims (e.g., p. 12 of the specification, paragraph 2).

Moreover, while the obviousness of controls may be present to the Artisan, it is noted that obviousness does not suffice for a demonstration of the invention.

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Hence, at best, within the scope of the invention claimed, the Artisan would only have understood Applicant to have been in possession of that embodiment described, with the same materials and method steps and subjects, in the Example.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons necessitated by the amendments. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is directed to generating subjects with a net positive positive energy balance by overfeeding, terminating the overfeeding, and identifying gene expression during a period of time following the termination, wherein the subject returns to a neutral energy balance during the period of time in which identification of gene expression occurs.

Applicant has not identified where in the specification or claims as filed support is found, either explicit or implicit, for such generic claim, except by broad aversion (argument, p. 1). Moreover, a review by the Examiner has found no support, either explicit or implicit for such generic claim. Therefore, the Artisan could not determine that Applicant had possession of such claimed invention at the time of invention.

Hence, these claims are rejected for comprising new matter. Moreover, it is noted that obviousness does not substitute for providing proper written description.

Claim Rejections - 35 USC § 112 – enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 remain rejected, and Claims 14 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record and the reasons provided below. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's newly amended claims 1-12 encompass overfeeding 3 separate groups, albeit calling two of the groups "volume matched" or overfeeding 1 group and starving two other groups by force feeding volume-matched saline (e.g., examples), along with subsequent ad libitum feeding in two groups, while pair-feeding the third group with that of the first.

The problems with these claims, along with the problems with developing a strategy or target, appear in that the controls still would not predict each condition, as in either case, the rats are all overfed and allowed to rebound together, or, in the case of saline, the control rats are underfed, and so, it would not be predicted whether such target was for any disorder, as no control exists of normal fed rats. Hence, these claims, being improperly controlled, would not enable any finding of potential target.

Claim 14 encompasses an overfeeding, with identification of gene expression following termination of the overfeeding, wherein the subject returns to a neutral energy balance during the period of time of identification of gene expression. Such necessarily does not equate with

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identification of changes in gene expression, and the change in energy balance is not necessarily due to the subject's preference. Further, as noted previously, without a control, and only testing a single animal, certainly does not reasonably predict a target or a strategy, for reasons of record.

Further, in all of these claims, the analysis is broad, and in claims 1-13 encompasses analyses performed prior to any treatments, as indicated by claim 4.

Still further, Applicant has failed to provide any more limitation on how such treatment is developed from any specific gene expression identification, or even how a target is developed from such gene expression. Even still further, the analysis is so broad as to encompass anything, and such is not commensurate with logic. To wit simple identification of a gene expression in the animal would not mean anything, it would have to have some correlative difference with the feeding regimens that would predict a specific therapeutic strategy or a successful target for a therapy commensurate with the scope of the claims.

To help applicant, because it appears that their claims are extremely broad, and not enabled, much less for the scope claimed, Applicant is advised to amend the claims commensurate with how any specific gene is identified, and when it is therefore predictive of any specific target/strategy. For example, the Examiner recommends language similar to "a change in gene expression, wherein when it is expressed at higher levels in group X at time 1 and decreases to an equal level of that expressed in group Y at time 2, indicates a gene which is correlated with condition Z.", although Applicant must also have proper support for their claimed limitations in the specification and claims as originally filed.

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It is noted that the following art rejections even in light of the lack of enablement, and they are applied because of the breadth of Applicant's claims as well as the fact that the Art does not require the claimed invention to be enabled or patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6-8, and 9-13 remain rejected under 35 U.S.C. 102(a), and under 35 U.S.C. 102(e), as being anticipated by US Patent Publication No. 2002/0041870 to Wu, published 4/11/02, claiming priority to 7/26/00.

With regard to Claim 1, 4, and 13, Wu teaches identification of differentially expressed genes in the hypothalamus due to overfeeding regimens (EXAMPLE 1). Further, the various methods for producing overfed animals describe providing diets over 100% of normal diet (paragraph 0151). With regard to the termination of overfeeding, such would necessarily occur at the termination of the experiment, amounting to the animals all eating ad libitum amounts of food, which would be equivalent to force feeding the ad libitum amount in group 3.

With regard to Claim 6-8, Wu describes identifying the gene expression in the hypothalamus (EXAMPLE 1; paragraph 00293).

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With regard to Claim 9, Wu describes isolating RNA and analyzing the levels of expression of such RNA (paragraphs 0154-0155), and further, that the RNAs expressed are selected based on the level of expression (e.g., paragraph 0293), which necessarily defines the target.

With regard to Claims 11-12, Wu's specific example is inherently a statistical analysis of the expression differences of RNAs in the hypothalamus.

Further, the differences between Wu and the presently rejected claims are interpreted to not-exist, as the volume-matched groups appear to be fed the same amounts as the non-volume-matched groups, and the pair-fed group would be equivalent to that of the other groups, as the normal amount eaten matches that of the ad libitum groups.

Response to Argument – anticipation US Pat Pub 2002/0041870

Applicant's response of 2/12/07 has been fully considered but is not found persuasive.

Applicant argues that Wu only is concerned with discovering the genes and polypeptides associated with obesity, but is not concerned with differential therapeutic approaches, and therefore does not anticipate the present invention (p. 9).

Such is not persuasive. Wu provides the same methods, and the same results, and identifies genes, much as Applicant's claims do. Applicant's claimed method provide no nexus to determine any therapeutic strategy, or identify targets for therapy, but simply discovers genes expressed differentially, and also those specifically differentially expressed during the overfeeding (e.g., Claim 4), as Wu's disclosure does. Moreover, as noted above, the differences above are noted, in their broadest interpretation to encompass the same scope previously rejected.

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Applicant argues that Wu is teaching obesity per se, while Applicant's invention is drawn to correlating weight loss that occurs as a result of a positive energy imbalance (pp. 9-10, paragraph bridging).

Such is not persuasive. Applicant's claims encompass gene expression during the overfeeding regimen, and do not require any specific correlates, but only a generic analysis of gene expression. As such, Wu necessarily still anticipates the claims.

Applicant broadly argues that Wu does not teach each and every element (p. 10).

Such is not persuasive. As noted above, the groups of subjects claimed can be interpreted to be the same, and hence, Wu still anticipates the claims.

It is recommended that Applicant make clear that the analysis is of the differences in gene expression subsequent to the overfeeding regimen, commensurate with their arguments, and thereby providing two different controls for comparison of normal.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Seeley, et al. (1996) American Journal of Physiology: Regulatory, Integrative, and Comparative Physiology, 40(3): R819-R823, ABSTRACT ONLY.

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The Examiner apologizes for the absence of the cited article, but he could not obtain a copy by the time the Action had to be responded to, and so, only the abstract is provided, however, the abstract is all that is need to demonstrate that the claim is anticipated, and luckily, the Inventor Seeley is the primary Author, and hence, is well acquainted with the article.

With regard to Claim 14, Seeley teaches involuntary overfeeding of rats, termination of such overfeeding, and identifying gene expression by mRNA, in such rats when allowed 3 days to recover such that weight returned to the level of controls (e.g., ABSTRACT). Hence, Seeley anticipates the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2002/0041870 to Wu, published 4/11/02, claiming priority to 7/26/00, and Hagan, et al. (1999) J. Neuroscience, 19(6): 2362-67.

Response to Argument – Obviousness, Wu/Hagan

Applicant's argument of 2/12/07 have been fully considered but are not found persuasive.

Applicant argues the same arguments to Wu as discussed with regard to the anticipation rejection (pp. 10-11).

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Such is not persuasive for the same reasons as provided in the arguments under anticipation by Wu.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 9-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication No. 2002/0041870 to Wu, published 4/11/02, claiming priority to 7/26/00, and Rast, et al. (2000) Dev. Biol., 228: 270-86.

Response to Argument – obviousness, Wu/Rast

Applicant's argument of 2/12/07 has been fully considered but is not found persuasive.

Applicant argues that Wu's generic teaching of high-throughput methods, along with Rast's absence of discussion of obesity, makes these rejections improper (pp. 13-14).

Such is not persuasive. There is no teaching against any expectation of success. Rast teaches high-throughput array methods, and Wu teaches that high-throughput methods may be used. Hence, there exists a motivation to combine and expectation of success, hence, the rejection is necessarily proper. Wu does not have teach use of Rast's method, nor does Rast have to teach obesity, the motivation is there, and the expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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